REMARKS

Reconsideration of this Application is respectfully requested.

Claims 35-40 and 44-66 are pending. Claims 48-59 have been withdrawn from consideration as directed to a non-elected invention. New Claims 60-66 have been added. Claims 60-66 find support in original claims 35, 36, 37, 39, 44, 45 and 47, respectively. No new matter is added, and no new issues are raised. Entry of the amendments is requested.

In the Office Action of August 25, 2004 and the Advisory Action of January 26, 2005, the Examiner set forth a number of grounds for rejection. These grounds are addressed individually and in detail below.

Objection to the Specification

The specification stands objected to based on the use of the trademark GVAX. The specification has been amended as set forth above. A generic description for the term GVAX is provided in the specification at page 25, lines 30-34.

Rejections Under 35 U.S.C. § 103(a)

Claims 35-39 and 44-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sanda et al. in view of Savarese and further in view of Thomas et al. for the reasons set forth on pages 4-6 of the outstanding Office Action.

The Examiner specifically relies upon Sanda et al. as the primary reference. Sanda et al. is directed to an animal model that relies on a malignant rat prostate tumor line and the use thereof in a rat model which does not use the claimed cell lines. Accordingly, the rejection fails on two important points, the reference is directed to a rat model while the claims specifically refer to a human immune response, which necessarily cannot occur in a rat. Sanda et al. can not

teach a human humoral immune response to a human prostate tumor-associated antigen in a human subject when they don't teach or suggest a human antigen. Further Sanda et al. do not describe the claimed LnCaP, PC3 or DU145 cell lines (i.e. there is no source of the antigens for the claimed immune response).

Applicants respectfully disagree with the Examiner's argument that the combined references teach the claimed invention. The Examiner states that "Sanda teaches that vaccine compositions comprising irradiated prostate cancer cells (i.e. proliferation incompetent) genetically engineered to secrete granulocyte macrophage colony stimulating factor (GM-CSF) is effective for treating anaplastic, hormone refractory prostate cancer." The Examiner acknowledges that the primary reference does not teach LnCaP, PC3 or DU145, however he states that the secondary reference Savarese et al. teaches that LnCaP, PC3 and DU145 are well known prostate cancer cell lines and how to culture them. The Examiner further acknowledges that taken together the primary and secondary references fail to provide a motivation to one of skill in the art to make the claimed cell lines.

In making the obviousness rejection, a tertiary reference (Thomas et al.) is relied upon for the teaching that whole tumor cell vaccines engineered to secrete GM-CSF induce potent systemic immune responses, that primary autologous human tumor cells have been used in clinical trials but have been found impractical and that allogeneic vaccines are a good idea. Applicants submit the Examiner is misinterpreting Thomas et al. Thomas et al. does not teach or suggest prostate cancer associated antigens nor a humoral immune response to them. Thomas et al. discusses T cell immunity and MHC class I restricted antigens such as tumor antigens. One of skill in the art would appreciate that T cell immunity and MHC class I restricted antigens is generally interpreted to refer to cell-mediated immunity which is mediated by T-lymphocytes. In contrast, one of skill in the art would appreciate that the claimed compositions are directed to

generating humoral immunity which is generally understood to involve the production of antibody molecules in response to an antigen and is mediated by B-lymphocytes.

Furthermore, the CAFC in In re Sang Su Lee states, teaching of references can be combined only if there is some suggestion or incentive to do so. In re Sang Su Lee (Fed. Cir. January 18, 2002) (quoting ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed. Cir. 1984). Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. Id.

Applicants submit that the Examiner is attempting to create a hindsight reconstruction of the instant invention by piecing together references. As stated in In re Fritch, 23 USPQ2d 1780 (Fed. Cir. 1992), "[I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious".

Absent the invention as a roadmap, one of skill in the art would not combine a reference directed to a rat tumor model, Sanda et al., with a reference directed to human prostate cell lines, Savarese et al. and a reference directed to methods for generating a cellular immune response to a tumor antigen.

Even assuming arguendo that there was a motivation to combine the cited references, when taken together the combined references do not teach a GM-CSF- expressing LnCaP, PC3 and DU145 cell composition for use in generating a humoral immune response to a prostate tumor-associated antigen, let alone prostate antigens having the particular molecular weights cited in Claim 35. It follows that the current claims are not rendered obvious by the combination of cited art.

Accordingly, this ground of rejection has been obviated and withdrawal of the 35 U.S.C. § 103 rejection is respectfully requested.

CONCLUSION

Applicants respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact Linda R. Judge (Reg. No. 42,702) at 415-659-7035.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY U.S. LLP

REG. NO. 47,258

FOR Steven B. Kelber
Registration No. 30,073
Attorney of Record

Linda R. Judge
Registration No. 42,702

1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085